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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,072	04/07/2000	Yun Lin	00786/368002	9768

7590 05/21/2002

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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/545,072	Applicant(s) LIN ET AL.	
	Examiner Anne Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-39* is/are pending in the application.

4a) Of the above claim(s) *14 and 27-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13 and 15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendments to claims 1, 8-9, 12 and 16, the cancellation of claim 2, and the amendment of the abstract and title requested in Paper No. 14, filed 14 February, 2002, have been entered. Claims 1-39 are pending. Claims 14 and 27-39 are withdrawn from consideration. Claims 1, 3-13 and 15-26 are examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Response to Declaration

4. The rejection of claims 1-12 under 35 U.S.C. 102(a) as being anticipated by Rounsley et al is WITHDRAWN in light of the declaration submitted under 37 CFR 1.131 in which Yun Lin states that the nucleic acid of the instant invention was isolated prior to February, 1999, the date that Rounsley et al became available. Applicant has also submitted, as exhibit 1, a copy of an email from GenBank acknowledging receipt of a DNA sequence.

Response to Amendment

5. The cancellation of claim 2 obviates the objection of claim 9 as being a substantial duplicate thereof.

6. The objection to the disclosure is obviated by amendment to title and abstract to be fully descriptive of the invention as claimed.

7. The rejection of claim 12 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is WITHDRAWN in light of amendment to indicate that the cell is transformed.

8. The rejection of claims 12-13, 16-19 and 22 under 35 U.S.C. 102(b) as being clearly anticipated by Akama et al is WITHDRAWN in light of amendments to indicate that the plants of claims 12 and 16 are transformed with the nucleic acid. The rejection of claim 21 is not withdrawn, as the claim does not require that the seed be transformed with the nucleic acid.

9. The rejections of claims 1, 7 and 11-12 under 35 U.S.C. 102(b) as being anticipated by Mukai et al, claims 1, 3-6, 10-13, 15-18 and 21-26 under 35 U.S.C. 102(a) as being anticipated by Leborgne-Castel et al in light of Galili et al, and claims 1, 3-7, 10-13, 15-19 and 21-22 under 35 U.S.C. 102(b) as being anticipated by Lee et al are WITHDRAWN in light of amendments to claim 1 to indicate that the nucleic acid encodes an SSE polypeptide with at least 30% identity to SEQ ID NO:2.

10. The rejections of claims 1, 3-7, 10-13 and 15-26 under 35 U.S.C. 103(a) as being unpatentable over Lee et al in view of Dietrich et al, further in view of Gordon-Kamm et al and claims 1, 3-7 and 9 under 35 U.S.C. 103(a) as being unpatentable over Lee et al in view of Storozhenko et al are WITHDRAWN in light of amendments to claim 1 to indicate that the nucleic acid encodes an SSE polypeptide with at least 30% identity to SEQ ID NO:2.

Claim Rejections - 35 USC § 112

11. Claims 1, 3-13 and 15-22 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that encode SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that encode SSE proteins with 30% identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1-13 and 15-22.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that an application need not teach what is well-known in the art; thus, the application is enabled. Applicant urges that plant genes encoding SSE polypeptides could be identified and isolated by routine methods. Furthermore, Applicant urges that inoperative embodiments are permissible. Applicant argues that pg 22-25 of the specification provide clear instructions for identifying and characterizing other SSE genes, that pg 38-41 describe how to use these genes, and that pg 16 and 19-21 and Fig 4B teach screening assays for SSE genes (response pg 4-8).

This is not found persuasive because the cited pages of the specification do not teach which amino acids to modify. As the prior art does not teach SSE1 proteins, one cannot use any guidance of the prior art to make modifications in the gene of the instant invention, *e.g.*, by sequence comparison with homologs.

Given the lack of guidance provided by the specification and unpredictability associated with making amino acid substitutions, as discussed in the prior Office action, undue

experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding SSE proteins with 30% identity to SEQ ID NO:2. Making all possible single amino acid substitutions in an 367 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19^{366} nucleic acids. Because nucleic acids encoding proteins with 30% identity to SEQ ID NO:2 would encode proteins with many more than a single amino acid substitution, many more nucleic acids than that, *i.e.*, nucleic acids with many substitutions, would need to be made and analyzed.

12. Claims 23-26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that that it is well-known in the art that antisense technology works and that in most of the papers cited in the prior Office action antisense gene suppression was achieved (response pg 8-10).

This is not found persuasive because the cited references teach the many conditions in which antisense technology does not work. For example, as discussed in the prior Office action, Colliver et al showed that transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase resulted in transformants with *increased* levels of chalcone synthase transcripts (pg 519, left column, paragraph 2) and note other instances when this phenomenon has occurred (pg 519, right column, paragraph 1).

Applicant is invited to submit a declaration presenting data that show that antisense suppression of SSE in *Arabidopsis* and any other plant, using the gene of the instant invention, was successful in producing stress-resistant plants.

13. Claims 1, 3-13 and 15-26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1-13 and 15-26.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that the specification describes at least two structural features of the claimed sequences, hydrophilic and hydrophobic domains in Fig. 2B, and the complementation of the *sse1* and *pex1* mutations (response pg 10).

This is not found persuasive because the claims are not limited to nucleic acids encoding proteins with those hydrophilic and hydrophobic domains. Additionally, the specification does not teach the role that those domains in protein function. The specification on pg 8 does not define "SSE" by the ability of the nucleic acid encoding it to complement the *sse1* and *pex1* mutations, but as a protein that governs or regulates protein and oil body biogenesis. The nature of the regulation is not defined, and therefore may include proteins that turn on transcription, proteins that turn off transcription, proteins that prevent translation, proteins that are involved in protein folding, proteins that are involved in membrane transport, or proteins that have any of a number of other functions. Additionally, many different proteins perform each of those

functions, and even describing a protein as one involved in transport is not specific. The specification fails to describe the structural features of all such proteins.

See *In re Shokal,* 113 USPQ 283, (CCPA 1957) at pg 285

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

14. Claims 1, 3-13 and 15-26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in the rejection. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1-13 and 15-26. Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive.

Claims 1, 3-9 and 23 are indefinite in their recitation of the abbreviation "SSE". Applicant urges that the specification teaches that the SSE polypeptide is one that is encoded by a gene that when mutated produces the shrunken seed mutation, which is defined on pg 16, line 12, through pg 17, line 22, of the specification (response pg 11). This is not found persuasive because the protein encoded by this gene would be SSE1.

Claim 8 is indefinite for its recitation of "low stringency" as those hybridization conditions are not specified. Applicant argues that low stringency hybridization conditions are defined on pg 24, lines 13-22, of the specification (response pg 11). This is not found persuasive

because this part of the specification states that low stringency hybridization conditions include any of several exemplary conditions and that other, unspecified conditions are included. Thus, exactly what conditions are low stringency is unclear.

Claim Rejections - 35 USC § 102

15. Claim 21 remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by Akama et al. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 12-13, 16-19 and 21-22.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that claim 1 has been amended to claim a nucleic acid encoding an SSE polypeptide with at least 30% identity to SEQ ID NO:2, and Akama et al does not teach this nucleic acid.

This is not found persuasive because the seeds taught by Akama et al would inherently comprise a nucleic acid encoding an SSE polypeptide with at least 30% identity to SEQ ID NO:2. It is suggested that the claim be amended to indicate that the seed is transformed with the nucleic acid.

16. Claims 8 and 11-12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Storozhenko et al (1996, FEBS Lett. 390:113-118). The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1-5, 7-9 and 11-12.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that claim 1 has been amended to claim a nucleic acid encoding

an SSE polypeptide with at least 30% identity to SEQ ID NO:2 and the protein taught by Storozhenko et al (HSP91) does not have 30% identity to that of SEQ ID NO:2 and the nucleic acid would not hybridize to SEQ ID NO:1. Applicant also urges that HSP91 does not directly affect formation or content of food storage reserves in *Arabidopsis* (response pg 12).

This is not found persuasive because a direct effect on formation or content of food storage reserves in *Arabidopsis* is not required by claim 8, nor is 30% identity of the encoded protein to that of SEQ ID NO:2. Storozhenko et al teach a cDNA from *Arabidopsis* that encodes an SSE polypeptide and that would hybridize under "low stringency conditions" to SEQ ID NO:1. Because heat shock proteins are involved in so many critical functions in the cell, including maintenance of the endoplasmic reticulum (pg 113, left column, paragraph 2), this nucleic acid, when expressed in a cell of a plant, would facilitate intracellular transport of storage protein and the formation of protein and oil bodies.

17. Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (1996, Mol. Gen. Genet. 252:11-19). The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1, 3-7, 10-13, 15-19 and 21-26.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that claim 1 has been amended to claim a nucleic acid encoding an SSE polypeptide with at least 30% identity to SEQ ID NO:2 and claim 8 is limited to an nucleic acid that hybridizes to SEQ ID NO:8 under low stringency.

This is not found persuasive because the definition of an SSE polypeptide on pg 8 of the instant specification is that it is a protein that governs or regulates protein and oil body biogenesis. Because HSP70 is involved in protein translocation into the ER and that proteins

transported into the ER form protein and oil bodies, Hsp70 is an SSE polypeptide. Lee et al teach transformation of *Arabidopsis* with a Hsp70 cDNA in an antisense orientation, and its effect on expression of the HSP70 and HSC70 genes (pg 12, right column, paragraphs 1-2; pg 13, left column, last paragraph, to pg 14).

Claim Rejections - 35 USC § 103

18. Claims 8, 10-13, 15-19 and 21-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al in view of Storozhenko et al. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 27 July, 2001, as applied to claims 1-13, 15-19 and 21-26.

Applicant's arguments filed 14 February, 2002, have been fully considered but they are not persuasive. Applicant urges that Lee et al does not meet the structural limitations of the claims because Lee et al do not teach a nucleic acid encoding an SSE polypeptide with at least 30% identity to SEQ ID NO:2. Applicant asserts that Storzhenko et al do not suggest isolating DNA molecules encoding SSE polypeptides as presently claimed nor do they suggest that antisense RNA could modify plant storage reserves (response pg 13-14).

This is not found persuasive because claim 8, upon which claims 10-13 and 15-19 depend, is drawn to a nucleic acid encoding an SSE polypeptide wherein the nucleic acid hybridizes under "low stringency" to SEQ ID NO:1; the nucleic acid of Storzhenko et al would do so. The nucleic acid of Lee et al would encode an SSE polypeptide by the definition on pg 8 of the instant specification.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

19. Claims 1, 3-7, 9 and 20 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding an SSE polypeptide with at least 30% identity to SEQ ID NO:2.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
May 15, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638